JUN - 6 2001

510(k) Summary: K001917

Parodi Catheter for Angiography (ParCA)

Date Prepared: May23, 2001

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter

ArteriA Medical Science, Inc.
The Presidio
Old Army Hedquarters
PO Box 29450
San Francisco, CA 94129-0450

B. Company Contact

Mark Kieras
Director, Regulatory Affairs
ArteriA Medical Science, Inc.
Phone: 978.463.4086
Fax: 978.463.4087

C. Device Name

Trade Name:	**Parodi Catheter for Angiography (ParCA)**
Common Name:	Balloon Occlusion Catheter
Classification Name:	Catheter, Intravascular Occluding, Temporary
Classification:	21 CFR 870.4450, MJN

D. Predicate Devices

ArteriA believes that the ParCA device is substantially equivalent to the:

- Boston Scientific Medi-Tech Occlusion Balloon Catheter, K781772, and
- MicroTherapeutics Equinox Occlusion Balloon System, K990487.

E. Description of Device

The Parodi Catheter for Angiography (ParCA) is a dual lumen, intravascular catheter with a compliant cuff balloon at the distal end for use during angiographic procedures. A radio-opaque marker is positioned under the balloon for fluoroscopic identification. The cuff balloon is inflated through a small dedicated lumen. The ParCA is provided with a Parodi Dilator (PD) to ease ParCA entry into and passage through the vasculature.

F. Indication for Use

The Parodi Catheter for Angiography (ParCA) is indicated for use as an intravascular occluding catheter with an inflatable balloon tip that is used for

temporary occlusion of vessels in angiography-related applications. The ParCA is indicated for use in the common and external iliac arteries, subclavian artery, innonimate artery and superficial femoral artery.

The ParCA is not indicated for use in the carotid arteries.

The ParCA is not indicated for use in the prevention of distal embolization during endovascular procedures.

G. Comparison of Technological Characteristics

ArteriA Medical Science, Inc. believes that the ParCA device is substantially equivalent in design, materials of construction, function and intended use as the Boston Scientific Medi-Tech Occlusion Balloon Catheter, K781772, and the MicroTherapeutics Equinox Occlusion Balloon System, K990487.

Mark Kieras
Director, Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2001

Mr. Mark Kieras
Director, Regulatory Affairs
ArteriA Medical Science, Inc.
22 Hill Street
Newburyport, MA 01950

Re: K001917
Parodi Catheter for Angiography (ParCA)
Regulation Number: 870.4450
Regulatory Class: II (two)
Product Code: 74 MJN
Dated: May 9, 2001
Received: May 10, 2001

Dear Mr. Kieras:

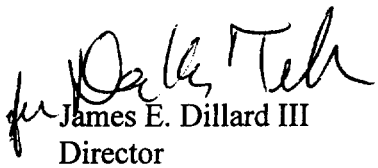
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K001917

Device Name : Parodi Catheter for Angiography (ParCA)

Indications for Use :

The Parodi Catheter for Angiography (ParCA) is indicated for use as an intravascular occluding catheter with an inflatable balloon tip that is used for temporary occlusion of vessels in angiography-related applications. The ParCA is indicated for use in the common and external iliac arteries, subclavian artery, innonimate artery and superficial femoral artery.

The ParCA is not indicated for use in the carotid arteries.

The ParCA is not indicated for use in the prevention of distal embolization during endovascular procedures.

(PLEASE DO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K001917